BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the adoption of Rule I through XV and the amendment of ARM 37.106.1902, 37.106.1906, and 37.106.1946 pertaining to outpatient crisis response facilities	)))))	NOTICE OF ADOPTION AND AMENDMENT

TO: All Interested Persons

1. On December 8, 2005, the Department of Public Health and Human Services published MAR Notice No. 37-363 at page 2428 of the 2005 Montana Administrative Register, issue number 23, regarding the proposed adoption and amendment of the above-stated rules. On April 20, 2006, the Department of Public Health and Human Services published MAR Notice No. 37-377 pertaining to the notice of extension of comment period on the proposed adoption and amendment of the above-stated rules, at page 1023 of the 2006 Montana Administrative Register, issue number 8.

2. The department has adopted new rules I (37.106.1975), III (37.106.1979), VI (37.106.1982), VIII (37.106.1987), IX (37.106.1989), X (37.106.1993), XI (37.106.1994), XII (37.106.1995), XIII (37.106.1996), XIV (37.106.1997), and XV (37.106.1990) as proposed.

3. The department has amended ARM 37.106.1946 as proposed.

4. The department has adopted the following rules as proposed but with the following changes from the original proposal. Matter to be added is underlined. Matter to be deleted is interlined.

RULE II (37.106.1976) OUTPATIENT CRISIS RESPONSE FACILITY: DEFINITIONS In addition to the definitions in 50-5-101, MCA, the following definitions apply to this subchapter:

(1) remains as proposed.

(2) "Outpatient crisis response facility" means an outpatient facility operated by a licensed hospital or a licensed mental health center that provides evaluation, ~~assessment,~~ intervention and referral for individuals experiencing a crisis due to serious mental illness or a serious mental illness with a co-occurring substance use disorder. The facility may not provide services to a client for more than 23 hours and 59 minutes from the time the client arrives at the facility. The facility must discharge or transfer the client to the appropriate level of care.

AUTH: 50-5-103, MCA
IMP: 50-5-103, MCA

RULE IV (37.106.1980) OUTPATIENT CRISIS RESPONSE FACILITY: ORGANIZATIONAL STRUCTURE (1) through (2) remain as proposed.

(3) Each outpatient crisis response facility shall employ or contract with a program supervisor ~~who is a licensed mental health professional~~ knowledgeable about the service and support needs of individuals with co-occurring mental illness and intoxication/addiction disorders who may be experiencing a crisis. The program supervisor must be site based.

(4) Each outpatient crisis response facility shall employ or contract with a licensed health care professional as defined in 50-5-101(34), MCA for all hours of operation. The licensed health care professional may be the program supervisor.

AUTH: 50-5-103, MCA
IMP: 50-5-103, MCA

RULE V (37.106.1981) OUTPATIENT CRISIS RESPONSE FACILITY: STAFFING AND OPERATIONS (1) through (5) remain as proposed.

(6) The facility must maintain locked and secured storage for all medications kept on site.

(6) through (10) remain as proposed but are renumbered (7) through (11).

~~(11)~~ (12) The facility must maintain progress notes for each client. The progress notes must be entered following the clinical intake assessment and updated ~~in a timely manner~~ by the end of each shift into the client's clinical record. The progress notes must describe the client's physical condition, mental status, and involvement in treatment services.

(12) through (13)(b) remain as proposed but are renumbered (13) through (14)(b).

AUTH: 50-5-103, MCA
IMP: 50-5-103, MCA

RULE VII (37.106.1983) OUTPATIENT CRISIS RESPONSE FACILITY: CLINICAL RECORDS (1) Each crisis response facility shall collect assessment data and maintain clinical records on all clients who receive services.

(2) Each facility must ensure the confidentiality of clinical records in accordance with the ~~Uniform Health Care Information Act, Title 50, chapter 16, part 5, MCA~~ Health Information Portability and Accountability Act (HIPAA).

(3) through (g) remain as proposed.

AUTH: 50-5-103, MCA
IMP: 50-5-103, MCA

5. The department has amended the following rules based on public comment. Adding the definition of these terms to ARM 37.106.1902 and 37.106.1906 rather than the rule in which the terms are used does not provide substantive change to the rules. Matter to be added is underlined. Matter to be deleted is interlined.

37.106.1902 MENTAL HEALTH CENTER: DEFINITIONS In addition to the definitions in 50-5-101, MCA, the following definitions apply to this subchapter:

(1) through (9) remain the same.

~~(10)~~ (14) "Inpatient ~~C~~crisis stabilization ~~program~~ facility" means 24 hour supervised treatment for adults with a mental illness for the purpose of stabilizing the individual's symptoms.

(11) through (14) remain the same but are renumbered (10) through (13).

(15) through (30) remain the same.

AUTH: 50-5-103, MCA
IMP: 50-5-103, 50-5-204, MCA

37.106.1906 MENTAL HEALTH CENTER: SERVICES AND LICENSURE

(1) through (3)(e) remain the same.

(4) A mental health center, with the appropriate license endorsement, may provide one or more of the following services:

(a) through (f) remain the same.

(g) an inpatient crisis stabilization ~~program~~ facility; ~~or~~

(h) an outpatient crisis response facility; or

~~(h)~~ (i) a comprehensive school and community treatment program.

(5) through (8)(e) remain the same.

AUTH: 50-5-103, MCA
IMP: 50-5-103, 50-5-204, MCA

6. The department has thoroughly considered all commentary received. The comments received and the department's response to each follow:

General Public Comments: Questions, Clarifications:

COMMENT #1: A facility that offers chemical dependence and mental health services objects that it was not given the opportunity to participate in the development of the proposed rules.

RESPONSE: The department disagrees. The department held a public hearing on the proposed rules on January 4, 2006. The public comment period was extended to May 5, 2006, to assure all entities or individuals had ample time to comment on the rule. The commentor submitted written testimony to the department. The department has followed all requirements of the Montana Administrative Procedure Act.

COMMENT #2: As they are, the rules are inadequate for the purpose they are intended to serve and will only serve to exacerbate the problems connected to the provision of services to individuals in crisis due to serious mental illness and especially those who have concomitant substance abuse issues.

RESPONSE: The department disagrees. The rules as proposed, and amended

following the comment period, will be adequate in the full continuum of mental health services. The proposed Outpatient Crisis Response Facility (OCRF) is specific to individuals in mental health crisis and will refer to other services in the continuum as patient need indicates. An OCRF is not intended to cover the broad array of all mental health needs in a community. The department feels the rule is adequate for its intended purpose.

COMMENT #3: The proposed rules need to be addressed by the department pursuant to 2-4-305, MCA. Requisites for Validity- authority and statement of reasons.

RESPONSE: The department agrees and is in compliance with the requirements found at 2-4-305, MCA.

COMMENT #4: Diverting individuals experiencing a crisis from hospital ERs to an OCRF may be a wholesale violation of the Emergency Medical Treatment and Active Labor Act (EMTALA).

RESPONSE: The department disagrees. EMTALA only applies to a patient presenting at a hospital emergency department. Emergency room (ER) staff would have an OCRF as an additional mental health service resource, if after a medical assessment the ER found it appropriate to transfer to the OCRF.

COMMENT #5: The department has no statutory authority providing for the adoption of the proposed rules to establish these outpatient services as a health care facility.

RESPONSE: The department disagrees. Section 50-5-101(23), MCA includes the term "mental health center" and "hospital" in the definition of a health care facility. The department clearly has the authority to promulgate rules for mental health centers and hospital services. Section 50-5-101(37), MCA defines a mental health center as "a facility providing services for the prevention or diagnosis of mental illness, the care and treatment of mentally ill patients, the rehabilitation of mentally ill individuals, or any combination of these services." The OCRF rules describe the requirements for a mental health service that would either be free standing or added to a mental health center facility license as an endorsement. Outpatient services are included under a hospital license as an outpatient service.

COMMENT # 6: A proposed site for provision of this outpatient service in Billings will not be located at one of the hospitals or the mental health center and therefore will not be a portion of one of those facilities. Consequently the proposed OCRF will not be a "health care facility" as defined in 50-5-101(23), MCA.

RESPONSE: The department disagrees. There are no requirements in state law mandating a single site for all services provided. Hospital and mental health services are not restricted to one all inclusive location or site. There are 16 licensed mental health center facilities with approximately 140 different satellite office service

locations. Additionally, several hospitals in the state of Montana are operating in two or more distinct locations under one license.

COMMENT #7: Because the OCRF will be an outpatient service and will not be a health care facility, as defined in statute, an intoxicated person would not be able to be transported to an OCRF by law enforcement. Even with the adoption of the proposed rules, law enforcement will still be required to transport an intoxicated person to a private treatment facility, a mental health center, or to the ER under the provisions of 53-24-303, MCA, treatment and services for intoxicated persons.

RESPONSE: The department disagrees. OCRF services are provided by a licensed mental health center or hospital under 50-5-101(23), MCA.

COMMENT #8: If an ambulance is called to transport an intoxicated person, the ambulance will have no choice but to transport the person to the emergency department of a hospital. If the medical condition of an intoxicated person is serious enough that the person needs transportation by an ambulance, then it is serious enough that the ambulance would be assuming substantial risk by transporting the patient to a low-level outpatient program rather than a hospital ER.

RESPONSE: The department agrees with this comment. Transportation should be provided to the nearest hospital ER department.

COMMENT #9: Many of the individuals who will be admitted to the proposed crisis response facility in Billings will be highly intoxicated individuals who may secondarily exhibit serious mental illness symptoms. Attempting to divert people in crisis to the low-level outpatient program described in the proposed rules could be life threatening to many of these individuals. At the very least, they are in need of immediate medical screening with implementation of medications to prevent life threatening withdrawal.

RESPONSE: The department disagrees. These rules are intended to allow communities to develop an OCRF as part of a continuum of care and resources for meeting the needs of persons experiencing a psychiatric crisis. These rules are not specific to Billings. If an OCRF determines that services beyond the scope of the facility are required, transfer to an appropriate level of care will be initiated under the transfer agreement.

COMMENT #10: A reading of the rules does not indicate that any medical personnel are required to be on site at this facility to provide immediate medical screening, conduct a medical evaluation, or implement medications during the 23 hours and 59 minutes the patient can remain at the facility. The absence of any required staffing to include individuals, such as a licensed nurse, capable of assessing and consulting with a medical director regarding substance withdrawal seems to be a serious deficiency in these rules and compromises the safety of the clients of a crisis response facility established under the proposed rules.

RESPONSE: The department agrees and will amend the rule to indicate that a licensed health care professional as defined at 50-5-101(34), MCA must be on site during all hours of operation. A licensed health care professional means a licensed physician, physician assistant, advanced practice registered nurse, or registered nurse who is practicing within the scope of the license issued by the Department of Labor and Industry.

The department will strike the words in RULE IV (37.106.1980) OUTPATIENT CRISIS RESPONSE FACILITY: ORGANIZATIONAL STRUCTURE (3) Each outpatient crisis response facility shall employ or contract with a program supervisor ~~who is a licensed mental health professional~~ knowledgeable about the service and support needs … The department will add the following language to RULE IV (37.106.1980) OUTPATIENT CRISIS RESPONSE FACILITY: ORGANIZATIONAL STRUCTURE. New Section (4) Each outpatient crisis response facility shall employ or contract with a licensed health care professional as defined in 50-5-101(34), MCA for all hours of operation. The licensed health care professional may be the program supervisor.

COMMENT #11: The potential impact of the proposed rules on the distribution of liquor, beer, and wine taxes provided for in 53-24-206(3), MCA, may be an unintended consequence of the adoption of the proposed rules. The commentor strongly asserts that the proposed rules need to clearly provide that OCRFs are not chemical dependency programs and do not qualify for distribution of liquor, beer, and wine tax funds under 53-24-206(3), MCA.

RESPONSE: The department agrees. OCRF is a licensed health care facility under Title 50, MCA and is not eligible for receipt of distributed liquor, beer, and wine tax funds under 53-24-206(3), MCA.

COMMENT #12: The commentor respectfully submits that the proposed rules should be rejected in total.

RESPONSE: The department disagrees. These rules are intended to allow a community to develop an OCRF as part of a continuum of care and resources for meeting the needs of persons experiencing a psychiatric crisis.

RULE II (37.106.1976) Outpatient Crisis Response Facility: Definitions

COMMENT #13: In proposed Rule II(2) (37.106.1976) - "individuals experiencing a crisis due to serious mental illness or a serious mental illness with a co-occurring substance use disorder" - appears to fall within the definition of "emergency medical condition" as that term is defined in the EMTALA law at 42 USC 1395dd(e) and 42 CFR 489.24(b). Adoption of the proposed rules in an attempt to divert individuals suffering these medical conditions from hospital ERs to a low-level outpatient program appears to be contrary to the spirit if not the letter of EMTALA.

RESPONSE: The department disagrees. The adoption of the rule is not intended to

divert individuals suffering medical conditions from a hospital ER. ER services continue to be available. EMTALA does not apply to an OCRF.

COMMENT #14: The department should define the term "assessment".

RESPONSE: The department understands the commentor's concern and will strike the word "assessment" from RULE II (37.106.1976) OUTPATIENT CRISIS RESPONSE FACILITY: DEFINITIONS (2) Outpatient crisis response facility.

COMMENT #15: Does the term: "Outpatient crisis response facility" need to be defined in Rule II (37.106.1976) as well as in ARM 37.106.1902(10)?

RESPONSE: The department agrees and will add the definition of outpatient crisis response facility to ARM 37.106.1902.

COMMENT #16: Please consider adding the term: "Inpatient" to ARM 37.106.1902(10) and ARM 37.106.1906(4)(g) for clarity.

RESPONSE: The department agrees and will add the word "inpatient" to ARM 37.106.1902(10) and ARM 37.106.1906(4)(g) and will also add the term "outpatient crisis response" to ARM 37.106.1906(4)(h).

COMMENT #17: While a medical director is required under proposed Rule IV(2) (37.106.1980) to be available for consultation, the medical director is not required to be on site.

RESPONSE: The department agrees and refers the commentor to the changes to Rule IV as described in the response to Comment #10.

COMMENT #18: The mental health professional in proposed Rule IV(3) (37.106.1980) is required only to be knowledgeable about intoxication/addiction disorders and is not required to be qualified to address the needs or to assess signs and symptoms of substance withdrawal.

RESPONSE: The department disagrees. An OCRF is limited to a less than 24 hour service and is not intended to treat addiction disorders and/or substance withdrawal, but can refer to appropriate services. Pursuant to the changes described in the department's response to Comment #10, a licensed health care professional will be on site to assess the individual patient's needs for specialized services to treat substance withdrawal and to initiate an appropriate referral.

COMMENT #19: The lack of any staff-patient ratio requirement specifying the number of clients that the one required mental health professional may care for is a serious shortcoming of the rules. According to the proposed rules, a single licensed mental health professional could handle any number of crisis admissions since there is also no limit to the number of mental health clients that may receive services at a OCRF at any one time.

RESPONSE: The department disagrees. Please see the department's response to Comment #10. A licensed health care professional will be on site at all times. Additional staff resources can be accessed as patient census and acuity require.

COMMENT #20: The mental health professional in proposed Rule IV(3) (37.106.1980) is required only to be knowledgeable about intoxication/addiction disorders and is not required to be qualified to address the needs or to assess signs and symptoms of substance withdrawal.

RESPONSE: The department disagrees. An OCRF is limited to a less than 24 hour service and is not intended to treat addiction disorders and/or substance withdrawal, but can refer to appropriate services. Pursuant to the changes described in the department's response to Comment #10, a licensed health care professional will be on site to assess the individual patient's needs for specialized services to treat substance withdrawal and to initiate an appropriate referral.

RULE V (37.106.1981) Outpatient Crisis Response Facility: Staffing and Operation

COMMENT #21: Proposed Rule V(8)(b) (37.106.1981), provides that a client must be medically stable to be admitted to a crisis response facility with the exception of the individual's mental illness and substance use disorder. Nowhere in the rules is the potential need for detoxification considered or the need to have a transfer agreement for the purpose of providing detoxification services to individuals needing them. The commentor believes a transfer agreement with existing detoxification programs should be required unless it is the department’s intent to permit the crisis response facility to provide detoxification. This issue needs to be clarified.

RESPONSE: The department disagrees. An OCRF is not intended to provide detoxification services to a client as the facility is time limited to less than 24 hours. An OCRF may refer a patient into an existing detoxification program, an outpatient service or to an acute care admission depending upon the patient's acuity and medical needs.

COMMENT #22: How will a determination be made that a client is medically stable and who will make that determination? The EMTALA law is clear that a determination whether or not a patient is medically stable for transfer or discharge from an emergency may only be made by ER medical personnel. It can certainly not be made by a nonphysician mental health professional working at an OCRF.

RESPONSE: The department agrees that a determination of whether or not a patient is medically stable for transfer or discharge from an ER may only be made by ER medical personnel. The proposed rules do not require discharge from an ER into a OCRF unless the ER physician feels it is an appropriate discharge. Conversely, an OCRF may initiate the transfer agreement to emergency services.

COMMENT #23: An OCRF operated by a hospital would be a department of the hospital as described in 42 CFR 413.65. In that event, an individual brought to the OCRF would be considered to have presented to the emergency room of the hospital under the regulatory provisions of EMTALA, which defines "comes to the emergency department" to include an individual who is on hospital property located off the main hospital campus, 42 CFR 489.24 (b). In that instance, an individual brought to the OCRF would immediately have to be taken to the hospital ER for medical screening and the treatment necessary to stabilize the person's medical condition before the individual could be transferred.

RESPONSE: The department partially agrees. A patient that presents to a hospital based OCRF shall be screened and stabilized as required by 42 CFR 489.24(b) and transferred to appropriate hospital services. Individuals in need of emergency intervention will be transferred to the hospital emergency room for medical screening and treatment pursuant to the required transfer agreement described in Rule V(10) (37.106.1981). However, An OCRF is not intended for emergency intervention.

COMMENT #24: Proposed Rule V(10) (37.106.1981) would require that a facility ensure that inpatient care is available through a transfer agreement for clients in need of a higher level of care. It is not clear, however, that the requirement addresses detoxification services outside of hospital settings which can and should be utilized. The commentor believes that transfer agreements should be required of an OCRF for at least acute hospitalization, crisis stabilization, transitional living resources and detoxification. Simply maintaining a "list" of agencies is inadequate.

RESPONSE: The department disagrees. The facility can utilize any of the services available to the community. The rule does require a transfer to acute service if required by a patient in crisis for either mental health issues or acute medical needs. The proposed rule does not prohibit an OCRF from transferring as appropriate to a acute care hospital, an inpatient crisis stabilization facility, transitional living resources, or other facility providing detoxification services.

COMMENT #25: Nowhere in the proposed rules is there a requirement for a medically qualified individual to make a determination regarding the medical appropriateness for this level of care. This determination must be made by a qualified medical professional.

RESPONSE: The department agrees and has amended the proposed rule as described in its response to Comment #10.

COMMENT #26: Rule V(7) (37.106.1981) staff ratio seems to need some parameters. Programs often invest in administrative people, saving money on the nonprofessionals. All programs should establish an acuity ratio that

meets with bureau approval. The ratio would vary from facility to facility because of the physical design differences, but the facility ratio should be determined from outside the program.

RESPONSE: The department disagrees. Please see the department's response to Comment #10. A licensed health care professional will be on site at all times. Additional staff resources can be accessed as patient census and acuity require. It is not possible to predict the staffing requirements as patient acuity and needs will vary on an individual basis. Facility staffing is required to meet the needs of the patients.

COMMENT #27: Rule V(10) (37.106.1981) progress notation should be completed each shift. If it is not done on each shift, it will not get done.

RESPONSE: The department agrees. Rule V (11) (37.106.1981) applies to progress notes, and will change "~~in a timely manner~~" to the words "by the end of each shift".

RULE VII (37.106.1983) Outpatient Crisis Response Facility: Clinical Records

COMMENT #28: In proposed Rule VII(2) (37.106.1983), an OCRF would be required to comply with the Uniform Health Care Information Act, Title 50, chapter 16, part 5, MCA (UHCIA). Since October 1, 2003, however, the UHCIA is no longer applicable to health care providers that are subject to the HIPAA privacy standards. If an OCRF is subject to HIPAA privacy standards, and most if not all would be, the OCRF will not fall within the jurisdiction of the UHCIA, but rather, will be covered by the HIPAA privacy standards and Title 50, chapter 16, part 8, MCA.

RESPONSE: The department agrees and will change RULE VII (37.106.1983) OUTPATIENT CRISIS RESPONSE FACILITY: CLINICAL RECORDS (2) as follows: The department will strike the term: " … in accordance with ~~Health Care Information Act, Title 50, Chapter 16, part 5, MCA"~~ and will insert the words: "… in accordance with the Health Information Portability and Accountability Act (HIPAA)."

COMMENT #29: Proposed Rule VII(2)(e) (37.106.1983), would require the patient's medical record to contain medication orders from the prescribing physician and documentation of all medication administration; however, there is no requirement in the proposed rules for qualified staff to perform these functions. Further, there are no rules regarding medication storage, pharmaceutical management, etc. There are no guidelines for what medications may be administered, including medications used in detoxification.

RESPONSE: The department partially agrees. Medication orders may only be written by a licensed physician, physician assistant within the scope of license, or an advanced practice registered nurse. Pharmaceutical management requirements are defined by the Board of Pharmacy. The department will add the following to RULE V (37.106.1981) OUTPATIENT CRISIS RESPONSE FACILITY: STAFFING AND

OPERATIONS. Insert (6) and renumber accordingly "The facility must maintain locked and secured storage for all medications kept on site."

RULE VIII (37.106.1996) Outpatient Crisis Response Facility: Client Assessments

COMMENT # 30: I do not believe the facility will be able to perform assessments as suggested within the 23 hours, 59 minutes allotted. A valid assessment cannot be conducted while a person is under the influence. If a client is drunk or high, an assessment cannot be conducted until they are no longer under the influence of chemical substances. The department should consider changing the requirements to a 72 hour model of crisis response.

RESPONSE: The department agrees. The word "assessment" was stricken from RULE II (37.106.1976) OUTPATIENT CRISIS RESPONSE FACILITY; DEFINITIONS. An OCRF is not intended to be a chemical dependency treatment facility. It is intended to provide immediate response to individuals in psychiatric crisis to stabilize and determine the appropriate service for the patient's need. The department feels that the continuum of care for longer than 23 hours and 59 minutes is already authorized by statute. A 72-hour model of crisis response is available at a licensed inpatient crisis stabilization program, a behavioral health inpatient facility, or at a hospital.

/s/ Russell E. Cater
Rule Reviewer

/s/ Russell E. Cater for
Director, Public Health and Human Services

Certified to the Secretary of State May 8, 2006.